

CALIFORNIA OFFICE OF ADMINISTRATIVE LAW

SACRAMENTO, CALIFORNIA

ENDORSED FILED
IN THE OFFICE

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In re:) 1988 OAL Determination No. 11
Request for Regulatory)
Determination filed by) [Docket No. 87-017] EU
the California Nurses)
Association concerning the)
Respiratory Care Examining)
Committee's "opinion")
dated April 10, 1987 (re-)
garding the administration)
of parenteral medications)
by respiratory care prac-)
titioners)¹)
Determination Pursuant to
Government Code Section
11347.5; Title 1, California
Code of Regulations
Chapter 1, Article 2

Determination by:



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SYNOPSIS

The issue presented to the Office of Administrative Law was whether the Respiratory Care Examining Committee's "opinion," dated April 10, 1987, stating that parenteral medications may under certain conditions be administered by a respiratory care practitioner, is a "regulation" required to be adopted in compliance with the Administrative Procedure Act.

The Office of Administrative Law has concluded that the above noted "opinion" is a "regulation" required to be adopted in compliance with the Administrative Procedure Act because the "opinion" implements, interprets, or makes specific statutory law or supplements regulatory law that governs respiratory care practitioners.

THE ISSUE PRESENTED 2

The Office of Administrative Law ("OAL") has been requested to determine³ whether the Respiratory Care Examining Committee's ("Committee") "opinion," dated April 10, 1987, stating that respiratory care practitioners ("RCP") may under certain conditions administer parenteral medications, is a "regulation" as defined in Government Code section 11342, subdivision (b), and therefore violates Government Code section 11347.5, subdivision (a).⁴

THE DECISION 5,6,7,8

The Office of Administrative Law finds that the above noted "opinion" (1) is subject to the requirements of the Administrative Procedure Act (APA),⁹ (2) is a "regulation" as defined in the APA, and (3) therefore violates Government Code section 11347.5, subdivision (a).

I. AGENCY, AUTHORITY, APPLICABILITY OF APA; BACKGROUND

Agency

The Respiratory Care Examining Committee was created by the Legislature in 1983 in the Respiratory Care Practice Act ("Act").¹⁰ It "is the newest regulatory licensing board in the Department of Consumer Affairs."¹¹ The Committee is under the jurisdiction of the Board of Medical Quality Assurance, Division of Allied Health Professions, of the Department of Consumer Affairs.¹²

The Committee is responsible for the enforcement and administration of the Act, which includes, inter alia, (1) examination and certification of respiratory care practitioners, (2) inspection of respiratory care facilities, and (3) issuance, suspension and revocation of certificates.

Authority ¹³

Business and Professions Code section 3722 provides:

"The [Committee] shall adopt such regulations as may be necessary to effectuate the provisions of [the Act]. In adopting rules and regulations, the [Committee] shall comply with the [APA]." [Emphasis added.]

Applicability of the APA to Agency's Quasi-Legislative Enactments

The APA applies to all state agencies, except those "in the judicial or legislative departments."¹⁴ Since the Committee is in neither the judicial nor the legislative branch of state government, we conclude that APA rulemaking requirements generally apply to the Committee.¹⁵

In any event, Business and Professions Code section 3722, cited above, specifies that the Committee's rulemaking is subject to the requirements of the APA.

General Background

To facilitate understanding of the issues presented in this proceeding, we discuss pertinent statutory and regulatory history as well as the undisputed facts and circumstances giving rise to the present Determination.

Prior to the Act, the duties of respiratory therapy personnel included, but were not limited to,

"administration of various types of gas, aerosol, intermittent positive-pressure breathing treatments; assisting with long-term continuous artificial

ventilation; cleans, sterilizes and maintains respiratory therapy equipment; and maintains records of patients' therapy."¹⁶

In 1983, the Legislature enacted Business and Professions Code sections 3701 and 3702. The Legislature declared in section 3701 that the practice of respiratory care

"... affects the public health, safety, and welfare and is to be subject to regulation and control in the public interest to protect the public from the unauthorized and unqualified practice of respiratory care

"... It is the intent also to recognize the existence of overlapping functions between physicians and surgeons, registered nurses, physical therapists, respiratory care practitioners, and other licensed health care personnel, and to permit additional sharing of functions within organized health care systems."¹⁷

Business and Professions Code section 3702 defines "Respiratory care." In part, section 3702 provides:

"Respiratory care as a practice means a health care profession employed under the supervision of a medical director in the therapy, management, rehabilitation, diagnostic evaluation, and care of patients with deficiencies and abnormalities which affect the pulmonary system and associated aspects of cardiopulmonary and other systems functions, and includes all of the following:

(a)

(b) Direct and indirect respiratory care services, including but not limited to, the administration of pharmacological and diagnostic and therapeutic agents related to respiratory care procedures necessary to implement a treatment, disease prevention, pulmonary rehabilitative or diagnostic regimen prescribed by a physician and surgeon.

(c)

(d) The diagnostic and therapeutic use of any of the following, in accordance with the prescription of a physician and surgeon: . . . pharmacologic agents related to respiratory care procedures; . . .

(e)" [Emphasis added.]

Dorland's Illustrated Medical Dictionary¹⁸ defines the term "parenteral" as meaning "not through the alimentary canal [i.e., orally] but rather by injection through some other

route, as subcutaneous, intramuscular, intraorbital, intracapsular, intraspinal, intrasternal, intravenous, etc."¹⁹ (Emphasis added.) OAL was unable to find a statute or a court case defining "parenteral," nor did the Committee provide a definition of "parenteral" in its Response to the Request for Determination. Therefore, for purposes of this Determination, we find that "parenteral medications" means those medications administered intramuscularly, intraspinally, intravenously, etc., but not orally.

In November 1986, the Committee received one of the first inquiries asking whether the Act authorized certified respiratory care practitioners to administer parenteral medications. Another inquiry followed in January 1987. In its Response to this Request for Determination, the Committee explained that "In order to respond to the inquiry, the Committee developed the April 10, 1987 opinion" ²⁰ In the "opinion" the Committee states

"that parenteral medications may be administered by a Respiratory Care Practitioner subject to the following conditions:

1. An approved Respiratory Care Protocol^[21] to administer parenteral medications must exist within the employer's place of business and must include the following:
 - a. Minimal education required
 - b. The approved classes of medications which may be administered
 - c. A formal training and certification program which includes each class of medication approved for administration. Such training must be acceptable for continuing education hours by the [Committee]. A minimum of four (4) CE hours is required.

Successful completion of a course in pharmacology of no less than one (1) semester hour offered by an accredited college or university may be accepted in lieu of the CE requirement.

2. The administration of parenteral medications must be in the physical presence of a physician." [Emphasis added.]

As early as June 1987, the California Nurses Association ("CNA") attempted to persuade the Committee to formally adopt the "opinion" concerning the administration of parenteral medications by RCPs in accordance with the APA.²² The Committee's Executive Officer responded to CNA's request by stating that the Committee "declines to adopt its response [i.e., "opinion"] as an administrative regulation" ²³

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CNA then filed a Request for Determination with OAL on October 6, 1987, challenging the "opinion" and arguing that the "opinion" is "a regulation as defined by Government Code section 11342, subdivision (b)" which "[failed] to comply with the adoption and filing requirements of the California [APA]." CNA alleges that the "opinion"

"[interprets] Business and Professions Code Sections 3701 and 3702. There are no existing regulations which further interpret or make clear the scope of practice of respiratory care practitioners under the applicable practice act."²⁴

CNA further stated "that the Committee exceeded the scope of its authority when it ruled that RCPs can administer dangerous and controlled substances via parenteral route [Par.] [This] unauthorized expansion of the RCP's scope of functions will seriously jeopardize the health, welfare, and safety of consumers in the state."²⁵

On June 6, 1988, OAL received the Committee's Response to the Request.²⁶

II. DISPOSITIVE ISSUES

There are two main issues before us:²⁷

- (1) WHETHER THE CHALLENGED RULE IS A "REGULATION" WITHIN THE MEANING OF THE KEY PROVISION OF GOVERNMENT CODE SECTION 11342.
- (2) WHETHER THE CHALLENGED RULE FALLS WITHIN ANY ESTABLISHED EXCEPTION TO APA REQUIREMENTS.

FIRST, WE INQUIRE WHETHER THE CHALLENGED RULE IS A "REGULATION" WITHIN THE MEANING OF THE KEY PROVISION OF GOVERNMENT CODE SECTION 11342.

In part, Government Code section 11342, subdivision (b) defines "regulation" as:

" . . . every rule, regulation, order or standard of general application or the amendment, supplement or revision of any such rule, regulation, order or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure" [Emphasis added.]

Government Code section 11347.5, authorizing OAL to determine whether or not agency rules are "regulations," provides in part:

"(a) No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction [or] . . . standard of general application . . . which is a regulation as defined in subdivision (b) of section 11342, unless the guideline, criterion, bulletin, manual, instruction [or] . . . standard of general application . . . has been adopted as a regulation and filed with the Secretary of State pursuant to [the APA]"
[Emphasis added.]

Applying the definition of "regulation" found in Government Code section 11342, subdivision (b) involves a two-part inquiry:

First, is the informal rule either

- o a rule or standard of general application or
- o a modification or supplement to such a rule?

Second, has the informal rule been adopted by the agency to either

- o implement, interpret, or make specific the law enforced or administered by the agency or
- o govern the agency's procedure?

The answer to the first part of this inquiry is "yes."

For an agency rule or standard to be "of general application" within the meaning of the APA, it need not apply to all citizens of the state. It is sufficient if the rule applies to all members of a class, kind or order.²⁸ It has, for instance, been judicially held that "rules significantly affecting the male prison population" are of "general application."²⁹

The challenged rule at issue here is clearly a rule of general application. The Committee admits that "In each instance the inquirer [whose question is whether the administration of parenteral medications is within the scope of practice of an RCP] is provided a copy of the Committee's opinion."³⁰ (Emphasis added.) The rule also significantly affects all respiratory care practitioners in the state, not just the RCPs who are the subject of an inquiry. Before any RCP may administer parenteral medications, all the conditions set out in the "opinion" must be met, including obtaining the required minimum education and attending a minimum of four hours of a formal training and certification program which includes each class of medication approved for administration.

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The Requester points out that not only are RCPs affected by the "opinion," but it also affects physicians, nurses and employers of RCPs. First, the "opinion" requires the physician to be physically present when an RCP administers parenteral medication. Second, the "opinion" requires an approved "Respiratory Care Protocol" to be developed within the employer's place of business. The employer must develop policies and protocols through collaboration with, inter alia, administrators, physicians and surgeons, and registered nurses. (See definition of "respiratory care protocols" in note 21.) Third,

"since the required training must be acceptable for continuing education hours by the [Committee], nursing instructors and/or faculty involved in a formal training or certification program are required to meet the [Committee's] continuing education standards when teaching a class on medication approved for administration by RCPs."³¹

The Committee did not dispute these arguments presented by CNA.

We therefore conclude that the "opinion" is a standard of general application not only having a significant impact on RCPs, but also on their employers, as well as on physicians and nurses.³²

The "opinion" also meets the second prong of the "regulation" test. It implements, interprets and makes specific Business and Professions Code section 3702.³³ Section 3702 provides:

"Respiratory care as a practice means a health care profession employed under the supervision of a medical director in the therapy, management, rehabilitation, diagnostic evaluation, and care of patients with deficiencies and abnormalities which affect the pulmonary system and associated aspects of cardiopulmonary and other systems functions, and includes all of the following:

(a)

(b) Direct and indirect respiratory care services, including but not limited to, the administration of pharmacological and diagnostic and therapeutic agents related to respiratory care procedures necessary to implement a treatment, disease prevention, pulmonary rehabilitative or diagnostic regimen prescribed by a physician and surgeon.

(c)

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(d) The diagnostic and therapeutic use of any of the following, in accordance with the prescription of a physician and surgeon: . . . pharmacologic agents related to respiratory care procedures; . . .

(e)" [Emphasis added.]

The Committee argues that section 3702 reflects an "extensive and specific definition of the legally authorized scope of practice of an RCP" (Emphasis added.) Upon reading section 3702, OAL fails to find language specifying that "respiratory care" includes the "administration of parenteral medications."

The Committee further argues that subdivisions (b) and (d), of section 3702, cited above,

"clearly includes the administration of parenteral medications Subdivision (b) . . . states that respiratory care practice includes 'the administration of pharmacological * * * agents * * *'; subdivision (d) also states that the practice includes 'pharmacologic agents related to respiratory care procedures;'. . ." [Emphasis added.]

The definitions of "pharmacology" or "pharmacologic," as defined in Dorland's Medical Dictionary,³⁴ are as follows: (1) "Pharmacology" means "the science that deals with the origin, nature, chemistry, effects, and uses of drugs;" and (2) "Pharmacologic" means "pertaining to pharmacology or to the properties and reactions of drugs."

These definitions are similar to the definitions provided by the Committee from Schmidt's Attorneys' Dictionary of Medicine;³⁵ however, none of these definitions specifically include the administration of parenteral medications, i.e., the means or method of applying medications. In light of these definitions, we are not persuaded by the Committee's argument. OAL does not find section 3702 to "clearly" or "specifically" include within the definition of "respiratory care practice" the administration of parenteral medication.

Section 3702 is further implemented and made specific by the "opinion" in that the "opinion" requires the administration of parenteral medications by an RCP be performed in the physical presence of a physician. Section 3702 does not require the physical presence of a physician, but requires only that the "administration of pharmacological agents" be "prescribed by" or "in accordance with the prescription of a physician and surgeon."³⁶ (Emphasis added.)

The "opinion" further supplements the "Respiratory Care Practitioner Regulations" contained in Title 16 of the

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California Code of Regulations, sections 1399.300-1399.380. Article 3, titled "Education and Experience," of these regulations is blank--"Reserved" for future regulations. Article 5, titled "Continuing Education," requires each RCP "to complete 15 hours of approved continuing education every 2 years."³⁷ These 15 hours of continuing education are required in order for an RCP to renew his or her license. None of the sections in article 5 require the minimum of four hours of continuing education for training, in each class of medication approved for administration, required by the "opinion" in order to administer parenteral medications.

WE CONCLUDE that the "opinion" is a standard of general application and that it implements, interprets and makes specific Business and Professions Code section 3702.

SECOND, WE INQUIRE WHETHER THE CHALLENGED RULE FALLS WITHIN ANY LEGALLY ESTABLISHED EXCEPTION TO APA REQUIREMENTS.

Rules concerning certain activities of state agencies--for instance, "internal management"--are not subject to procedural requirements of the APA.³⁸

In this proceeding, the Committee argues that, even if the "opinion" was regulatory, such opinion is exempt under Government Code section 11343, subdivision (a)(3). Section 11343, subdivision (a)(3) provides in part:

"Every state agency shall:

- (a) Transmit to the office for filing with the Secretary of State a certified copy of every regulation adopted or amended by it except one which:

. . .

- (3) Is directed to a specifically named person or to a group of persons and does not apply generally throughout the state."

The two prongs of section 11343, subdivision (a)(3) must be met before this exemption would apply. The two prongs are:

1. Whether there is a specifically named person or group of persons, and
2. Whether the challenged rule does not apply generally throughout the state?

The challenged action by the Committee affects, at a minimum, all respiratory care practitioners who may administer parenteral medications. The fact that the "opinion" has only been issued to a number of persons who have made an inquiry does

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not make them "specifically named person[s] or a group of persons." Though individual members of this group may be identified, the group is nonetheless an "open class"³⁹ whose individual members are affected by the challenged rule.⁴⁰


In our analysis, supra, we have already concluded that the challenged rule applies generally statewide; hence, we find that the Committee's challenged rule does not meet either of the two prongs as set out above.

We therefore conclude that none of the recognized exceptions (set out in note 38) apply to the Committee's opinion.

III. CONCLUSION

For the reasons set forth above, OAL finds that the Respiratory Care Examining Committee's opinion, dated April 10, 1987, concerning the administration of parenteral medications by respiratory care practitioners under certain conditions, (1) is subject to the requirements of the APA, (2) is a "regulation" as defined in the APA, and (3) therefore violates Government Code section 11347.5, subdivision (a).

DATE: July 6, 1988


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- 1 This Request for Determination was filed by Hedy Dumpel, RN, JD, Acting Director for the California Nurses Association, Government Relations Office, 1100 Eleventh Street, Suite 200, Sacramento, CA 95814, (916) 446-5019. The Respiratory Care Examining Committee was represented by Mitchell C. Semer, Executive Officer, Respiratory Care Examining Committee, 1430 Howe Avenue, Sacramento, CA 95825, and Daniel Buntjer, Supervising Counsel, Department of Consumer Affairs, 1020 N Street, Sacramento, CA 95814, (916) 322-5252.

- 2 The legal background of the regulatory determination process --including a survey of governing case law--is discussed at length in note 2 to 1986 OAL Determination No. 1 (Board of Chiropractic Examiners, April 9, 1986, Docket No. 85-001), California Administrative Notice Register 86, No. 16-Z, April 18, 1986, pp. B-14--B-16; typewritten version, notes pp. 1-4. Since April 1986, the following published cases have come to our attention:

Wheeler v. State Board of Forestry (1983) 144 Cal.App.3d 522, 192 Cal.Rptr. 693 (overturning Board's decision to revoke license for "gross incompetence in . . . practice" due to lack of regulation articulating standard by which to measure licensee's competence); City of Santa Barbara v. California Coastal Zone Conservation Commission (1977) 75 Cal.App.3d 572, 580, 142 Cal.Rptr. 356, 361 (rejecting Commission's attempt to enforce as law a rule specifying where permit appeals must be filed--a rule appearing solely on a form not made part of the CCR); National Elevator Services, Inc. v. Department of Industrial Relations (1982) 136 Cal.App.3d 131, 186 Cal.Rptr. 165 (invalidating internal legal memorandum informally adopting narrow interpretation of statute enforced by DIR); Association for Retarded Citizens--California v. Department of Developmental Services (1985) 38 Cal.3d 384, 396, n.5, 211 Cal.Rptr. 758, 764, n.5 (court avoided the issue of whether a DDS directive was an underground regulation, deciding instead that the directive presented "authority" and "consistency" problems); Johnston v. Department of Personnel Administration (1987) 191 Cal.App.3d 1218, 1225, 236 Cal.Rptr. 853, 857 (court found that the Department of Personnel Administration's "administrative interpretation" regarding the protest procedure for transfer of civil service employees was not promulgated in substantial compliance with the APA and therefore was not entitled to the usual deference accorded to formal agency interpretation of a statute); Americana Termite Company, Inc. v. Structural Pest Control Board (1988) 199 Cal.App.3d 228, 244 Cal.Rptr. 693 (court found--without reference to any of the pertinent case law precedents--that the Structural Pest Control Board's

auditing selection procedures came within the internal management exception to the APA because they were "merely an internal enforcement and selection mechanism.")

Readers aware of additional "underground regulations" decisions--published or unpublished--are invited to furnish OAL with a citation to the opinion and, if unpublished, a copy. Whenever a case is cited in a regulatory determination, the citation is reflected in the Determinations Index (see note 38, infra).

- 3 Title 1, California Code of Regulations (CCR), (formerly known as California Administrative Code), section 121(a) provides:

"'Determination' means a finding by [OAL] as to whether a state agency rule is a regulation, as defined in Government Code section 11342, subdivision (b), which is invalid and unenforceable unless it has been adopted as a regulation and filed with the Secretary of State in accordance with the [APA] or unless it has been exempted by statute from the requirements of the [APA]."
[Emphasis added.]

- 4 Government Code section 11347.5 (as amended by Stats. 1987, c. 1375, sec. 17) provides:

"(a) No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a regulation as defined in subdivision (b) of Section 11342, unless the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule has been adopted as a regulation and filed with the Secretary of State pursuant to this chapter.

"(b) If the office is notified of, or on its own, learns of the issuance, enforcement of, or use of, an agency guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule which has not been adopted as a regulation and filed with the Secretary of State pursuant to this chapter, the office may issue a determination as to whether the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, is a regulation as defined in subdivision (b) of Section 11342.

"(c) The office shall do all of the following:

1. File its determination upon issuance with the

Secretary of State.

2. Make its determination known to the agency, the Governor, and the Legislature.
3. Publish a summary of its determination in the California Regulatory Notice Register within 15 days of the date of issuance.
4. Make its determination available to the public and the courts.

"(d) Any interested person may obtain judicial review of a given determination by filing a written petition requesting that the determination of the office be modified or set aside. A petition shall be filed with the court within 30 days of the date the determination is published.

"(e) A determination issued by the office pursuant to this section shall not be considered by a court, or by an administrative agency in an adjudicatory proceeding if all of the following occurs:

1. The court or administrative agency proceeding involves the party that sought the determination from the office.
2. The proceeding began prior to the party's request for the office's determination.
3. At issue in the proceeding is the question of whether the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule which is the legal basis for the adjudicatory action is a regulation as defined in subdivision (b) of Section 11342." [Emphasis added to highlight key language.]

- 5 As we have indicated elsewhere, an OAL determination pursuant to Government Code section 11347.5 is entitled to great weight in both judicial and adjudicatory administrative proceedings. See 1986 OAL Determination No. 3 (Board of Equalization, May 28, 1986, Docket No. 85-004), California Administrative Notice Register 86, No. 24-Z, June 13, 1986, p. B-22; typewritten version, pp. 7-8; Culligan Water Conditioning of Bellflower, Inc. v. State Board of Equalization (1976) 17 Cal.3d 86, 94, 130 Cal.Rptr. 321, 324-325 (interpretation of statute by agency charged with its enforcement is entitled to great weight). The Legislature's special concern that OAL determinations be given appropriate weight in other proceedings is evidenced by the directive contained in Government Code section 11347.5, subdivision

(c): "The office shall . . . [m]ake its determination available to . . . the courts." [Emphasis added.]

6 Note Concerning Comments and Responses

In general, in order to obtain full presentation of contrasting viewpoints, we encourage not only affected rulemaking agencies but also all interested parties to submit written comments on pending requests for regulatory determination. See Title 1, CCR, sections 124 and 125. The comment submitted by the affected agency is referred to as the "response." If the affected agency concludes that part or all of the challenged rule is in fact an "underground regulation," it would be helpful, if circumstances permit, for the agency to concede that point and to permit OAL to devote its resources to analysis of truly contested issues.

In the matter at hand, an additional comment from the Requester was submitted to OAL; the Committee submitted a Response to the Request for Determination. Both were considered in making this Determination.

7 If an uncodified agency rule is found to violate Government Code section 11347.5, subdivision (a), the rule in question may be validated by formal adoption "as a regulation" (Government Code section 11347.5, subdivision (b)) (emphasis added) or by incorporation in a statutory or constitutional provision. See also California Coastal Commission v. Quanta Investment Corporation (1980) 113 Cal.App.3d 579, 170 Cal.Rptr. 203 (appellate court authoritatively construed statute, validating challenged agency interpretation of statute.)

8 Pursuant to Title 1, CCR, section 127, this Determination shall become effective on the 30th day after filing with the Secretary of State. This Determination was filed with the Secretary of State on the date shown on page 1.

9 We refer to the portion of the APA which concerns rulemaking by state agencies: Chapter 3.5 of Part 1 ("Office of Administrative Law") of Division 3 of Title 2 of the Government Code, sections 11340 through 11356.

10 Statutes 1982, chapter 1344, section 1, page 5018, effective July 1, 1983 (AB 1287).

- 11 Agency's Response, p. 2.
- 12 Business and Professions Code section 3710. See also section 3704 of the Business and Professions Code.
- 13 We discuss the affected agency's rulemaking authority (see Gov. Code, sec. 11349, subd. (b)) in the context of reviewing a Request for Determination for the purposes of exploring the context of the dispute and of attempting to ascertain whether or not the agency's rulemaking statute expressly requires APA compliance. If the affected agency should later elect to submit for OAL review a regulation proposed for inclusion in the California Code of Regulations, OAL will, pursuant to Government Code section 11349.1, subdivision (a), review the proposed regulation in light of the APA's procedural and substantive requirements.

The APA requires all proposed regulations to meet the six substantive standards of Necessity, Authority, Clarity, Consistency, Reference, and Nonduplication. OAL does not review alleged "underground regulations" to determine whether or not they meet the six substantive standards applicable to regulations proposed for formal adoption.

The question of whether the challenged rule would pass muster under the six substantive standards need not be decided until such a regulatory filing is submitted to us under Government Code section 11349.1, subdivision (a). At that time, the filing will be carefully reviewed to ensure that it fully complies with all applicable legal requirements.

Comments from the public are very helpful to us in our review of proposed regulations. We encourage any person who detects any sort of legal deficiency in a proposed regulation to file comments with the rulemaking agency during the 45-day public comment period. Such comments may lead the rulemaking agency to modify the proposed regulation.

If review of a duly-filed public comment leads us to conclude that a regulation submitted to OAL does not in fact satisfy an APA requirement, OAL will disapprove the regulation. (Gov. Code, sec. 11349.1.)

- 14 Government Code section 11342, subdivision (a). See Government Code sections 11343 and 11346. See also 27 Ops.Cal. Atty.Gen. 56, 59 (1956).
- 15 See Poschman v. Dumke (1973) 31 Cal.App.3d 932, 943, 107 Cal.Rptr. 596, 609.

- 16 Senate Committee on Business and Professions, "Staff Analysis of AB 1287 (Tucker) as amended May 6, 1982," dated May 10, 1982, pp. 1-2. See also Enrolled Bill Report by the Department of Consumer Affairs, State and Consumer Services Agency, concerning AB 1287, September 1982, p. 3.
- 17 In Dabbs v. Cardiopulmonary Management ((1987) 188 Cal.App.3d 1437, 1443-1444, 234 Cal.Rptr. 129, 133), the court described the Respiratory Care Practice Act as "not only [reiterating] the general California concern for patients, but specifically addresses the need to regulate and control those who deal in respiratory care" because the practice of respiratory care "affects the public health, safety and welfare and as such requires regulation and control."
- 18 Twenty-sixth Edition (1981).
- 19 Id., p. 970.
- 20 Agency's Response, pp. 2-3.
- 21 Business and Professions Code section 3702 defines "Respiratory care protocols" as meaning "policies and protocols developed by a licensed health facility through collaboration, when appropriate, with administrators, physicians and surgeons, registered nurses, physical therapists, [RCPs], and other licensed health care practitioners." (Emphasis added.)
- 22 See letter dated June 5, 1987, addressed to Joseph Inch, Chairman of the Committee, from CNA, attached to the Request for Determination.
- 23 See letter dated July 7, 1987, addressed to CNA from Mitchell C. Semer, Executive Officer of the Committee, attached to the Request for Determination.
- 24 Request for Determination, p. 1.
- 25 See letter dated June 5, 1987, addressed to Joseph Inch, Chairman of the Committee, from CNA, attached to the Request for Determination.

- 26 In addition to several substantive arguments, which are discussed in the text of the Determination, the Committee argues that "to state what is or is not within the scope of practice of an RCP is really tantamount to a law enforcement decision of the [Committee]. . . . [The Committee] cannot, and should not, be required to reduce its prosecutorial discretion to administrative regulation." (Agency's Response, p. 7.)

We do not agree with the Committee on this point. Section 11347.5 provides "No state agency shall issue, . . . enforce, or attempt to enforce any guideline, . . . criterion, . . . instruction [or] . . . standard of general application . . . which is a regulation as defined in subdivision (b) of section 11342, unless the guideline, . . . criterion, . . . instruction [or] . . . standard of general application . . . has been adopted as a regulation and filed with the Secretary of State pursuant to [the APA]." (Emphasis added.) Even if we were to assume that the Committee's "opinion" was "tantamount to a law enforcement decision," section 11347.5 contains no exception for "prosecutorial discretions."

- 27 See Faulkner v. California Toll Bridge Authority (1953) 40 Cal.2d 317, 324 (point 1); Winzler & Kelly v. Department of Industrial Relations (1981) 121 Cal.App.3d 120, 174 Cal.Rptr. 744 (points 1 and 2); cases cited in note 2 of 1986 OAL Determination No. 1. A complete reference to this earlier Determination may be found in note 2 to today's Determination.
- 28 Roth v. Department of Veteran Affairs (1980) 110 Cal.App.3d 622, 167 Cal.Rptr. 552.
- 29 Stoneham v. Rushen I (1982) 137 Cal.App.3d 729, 735, 188 Cal.Rptr. 130, 135; Stoneham v. Rushen II (1984) 156 Cal.App.3d 302, 309, 203 Cal.Rptr. 20, 24; Faunce v. Denton (1985) 167 Cal.App.3d 191, 196, 213 Cal.Rptr. 122, 125.
- 30 Agency's Response, p. 3.
- 31 See additional comment dated May 16, 1988, from CNA, received by OAL on May 19, 1988, p. 2.
- 32 The Committee also argues that it was merely responding to an individual inquiry and therefore the "opinion" is not a

standard of general application. We are not persuaded by this argument.

The reason why a state agency issues a rule does not determine whether or not the rule is a standard of general application. A rule is a standard of general application if it applies to all members of a class, kind or order. (See Roth v. Department of Veteran Affairs (1980) 110 Cal.App.3d 622, 167 Cal.Rptr. 552.)

Also, Government Code section 11347.5 declares that "No state agency shall issue . . . any guideline, criterion, . . . [or] . . . standard of general application . . . which is a regulation as defined in subdivision (b) of section 11342, unless the guideline, criterion, . . . [or] standard of general application . . . has been adopted as a regulation and filed with the Secretary of State pursuant to [the APA]." (Emphasis added.) Hence, the mere issuance of the "opinion" violates section 11347.5.

- 33 For purposes of discussion, we will focus on Business and Professions Code section 3702. We conclude, however, that the "opinion" meets the definition of "regulation," as defined in the APA, in that it also implements, interprets and makes specific Business and Professions Code section 3701.

As stated previously in the text, section 3701 declares ". . . It is the intent also to recognize the existence of overlapping functions between physicians and surgeons, registered nurses, . . . [RCPs], and other licensed health care personnel, and to permit additional sharing of functions within organized health care systems." (Emphasis added.) The "opinion" implements and makes specific section 3701 by stating that RCPs may administer parenteral medications--an "additional function" which RCPs were not previously legally permitted to perform. Our experience has shown us that "overlapping functions" and "additional sharing of functions" often require supplementary rules and interpretations. (See 67 Ops.Cal.Atty.Gen. 122 (1984), Opinion No. 83-1007--April 4, 1984 (a certified registered nurse anesthetist may lawfully administer a regional anesthetic when ordered by and within the scope of licensure of a physician, dentist or podiatrist but not pursuant to a "standardized procedure").

- 34 Twenty-sixth edition, p. 1000.

- 35 See Agency's Response, p. 5, citing to Schmidt's Attorneys' Dictionary of Medicine, 1988 edition, volume 3, pare P-153: "'Pharmacologic' pertains to, or involves, 'pharmacology,'

which is defined as the science which deals with the properties and actions of medicines (drugs)."

- 36 Health and Safety Code section 11027 defines "prescription" as "an oral order for a controlled substance given individually for the person(s) for whom prescribed, directly from the prescriber to the furnisher or indirectly by means of a written order of the prescriber." (Emphasis added.)
- 37 Title 16, CCR, section 1399.350.
- 38 The following provisions of law may also permit rulemaking agencies to avoid the APA's requirements under some circumstances, but do not apply to the case at hand:
 - a. Rules relating only to the internal management of the state agency. (Gov. Code, sec. 11342, subd. (b).)
 - b. Forms prescribed by a state agency or any instructions relating to the use of the form, except where a regulation is required to implement the law under which the form is issued. (Gov. Code, sec. 11342, subd. (b).)
 - c. Rules that "[establish] or [fix] rates, prices or tariffs." (Gov. Code, sec. 11343, subd. (a)(1).)
 - d. Rules directed to a specifically named person or group of persons and which do not apply generally throughout the state. (Gov. Code, sec. 11343, subd. (a)(3).)
 - e. Legal rulings of counsel issued by the Franchise Tax Board or the State Board of Equalization. (Gov. Code, sec. 11342, subd. (b).)
 - f. Contractual provisions previously agreed to by the complaining party. City of San Joaquin v. State Board of Equalization (1970) 9 Cal.App.3d 365, 376, 88 Cal.Rptr. 12, 20 (sales tax allocation method was part of a contract which plaintiff had signed without protest); see Roth v. Department of Veterans Affairs (1980) 110 Cal.App.3d 622, 167 Cal.Rptr. 552 (dictum); Nadler v. California Veterans Board (1984) 152 Cal.App.3d 707, 719, 199 Cal.Rptr. 546, 553 (same); but see Government Code section 11346 (no provision for non-statutory exceptions to APA requirements); see International Association of Fire Fighters v. City of San Leandro

(1986) 181 Cal.App.3d 179, 182, 226 Cal.Rptr. 238, 240 (contracting party not estopped from challenging legality of "void and unenforceable" contract provision to which party had previously agreed); see Perdue v. Crocker National Bank (1985) 38 Cal.3d 913, 926, 216 Cal.Rptr. 345, 353 ("contract of adhesion" will be denied enforcement if deemed unduly oppressive or unconscionable).

The above is not intended as an exhaustive list of possible APA exceptions. Further information concerning general APA exceptions is contained in a number of previously issued OAL determinations. The quarterly Index of Regulatory Determinations is a helpful guide for locating such information. The Determination Index, as well as an order form for purchasing copies of individual determinations, is available from OAL, 555 Capitol Mall, Suite 1290, Sacramento, CA 95814, (916) 323-6225, ATSS 8-473-6225. The price of the latest version of the Index is available upon request. Also, regulatory determinations are published every two weeks in the California Regulatory Notice Register, which is available from OAL at an annual subscription rate of \$50.

39 See Faulkner v. California Toll Bridge Authority, supra, note 27, pp. 323-324.

40 See 1987 OAL Determination No. 7 (State Labor Commissioner, May 27, 1987, Docket No. 86-013), California Administrative Notice Register 87, No. 24-Z, June 12, 1987, pp. B-53--B54, typewritten p. 13; and 1987 OAL Determination No. 9 (Department of Corporations, June 30, 1987, Docket No. 86-015), California Administrative Notice Register 87, No. 29-Z, July 17, 1987, pp. B-40--B-41, typewritten pp. 14-15.

41 We wish to acknowledge the substantial contribution of Unit Legal Assistant Annemarie Starr in the preparation of this Determination.